

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
No. 1:18-cv-502

LLOYD BUFFKIN, *et al.*,

Plaintiffs,

v.

ERIK HOOKS, *et al.*,

Defendants.

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO CERTIFY CLASS

NOW COME Defendants Erik Hooks, Abhay Agarwal, Kenneth Lassiter, Paula Smith, and the North Carolina Department of Public Safety ("the Department") by and through the undersigned counsel, to oppose Plaintiffs' motion for preliminary injunction ("the Motion"), and state the following:

STATEMENT OF THE CASE

On June 15, 2018, Plaintiffs filed a class action complaint alleging that the Department's policies and practices for the treatment of hepatitis C ("HCV") violate the Eighth Amendment because they demonstrate deliberate indifference to the serious medical needs of the proposed class of prisoners. D.E. 1 at 2–3, 21. Plaintiffs claim that the Department's failure to provide HCV screening tests to all inmates, regardless of medical history, violates the inmates' Eighth Amendment rights. Plaintiffs further allege that the failure to provide all HCV-positive inmates, regardless of medical history, with direct-acting antiviral drugs ("DAAs") violates the Eighth Amendment. D.E. 1 at 2–3, 21. Finally, Plaintiffs contend that Defendants are violating the Americans with Disabilities Act ("ADA") by discriminating against HCV-positive inmates when

they do not provide DAAs to those inmates but do provide medically necessary treatment to individuals with other disabilities. D.E. 1 at 21–22.

Plaintiffs seek a declaratory judgment that 1) “Defendants’ policy of withholding DAA treatment from persons in DPS custody diagnosed with chronic HCV violates the Eighth Amendment and the ADA,” and 2) “Defendants’ failure to offer HCV screening to all persons in DPS custody violates the Eighth Amendment and the ADA.” D.E. 1 at 22. Plaintiffs also seek a permanent injunction that would order Defendants to 1) formulate an HCV treatment policy that meets current standards of care; 2) treat Plaintiffs and proposed class members with DAAs; and 3) provide Plaintiffs and proposed class members with HCV-related medical information, counseling on drug interactions, and ongoing medical care for complications and symptoms of HCV. D.E. 1 at 22–23. Finally, Plaintiffs have filed a motion for preliminary injunction asking that Defendants be ordered to: 1) implement a universal opt-out screening policy; 2) cease reliance on certain contraindications provided for in Defendants’ current policy; and 3) provide treatment with DAAs to the named plaintiffs and members of the purported class according to guidelines promulgated by the American Association for the Study of Liver Disease/Infection Diseases Society of America. D.E. 26 at 1–2.

On June 26, 2018, Plaintiffs moved to certify the following proposed class:

all current and future prisoners in DPS custody who have or will have chronic hepatitis C virus, at least twelve weeks remaining on their sentences, and have not been treated with direct-acting antiviral drugs.

D.E. 3 at 1.

FACTS

HCV Generally

HCV is a viral infection transmitted through a variety of methods, including sex,

intravenous drug use, and blood transfusions. D.E. 27-1 at ¶ 8. Acute HCV may be asymptomatic or cause mild symptoms such as fatigue, and may spontaneously clear an infected patient's blood. *Id.* at ¶ 9. The presence of the virus more than six months after infection, however, renders the condition chronic. Chronic HCV, too, may produce few discernible symptoms other than fatigue or other mild, non-specific complaints. *Id.* at ¶ 9; D.E. 1-1, ¶ 10. HCV progresses slowly, with fibrosis (scarring of the liver) and cirrhosis (severe scarring) occurring over a period of years or decades in some patients, while not at all with others. Affidavit of Anita Wilson, M.D., (“Wilson Aff.”) at ¶ 9 and Ex. C, p. 9;¹ D.E. 27-1 at ¶ 9. The rate of progression of fibrosis or cirrhosis varies markedly across individuals depending on the host and environmental and viral factors. Wilson Aff. at ¶ 12 and Ex. B, p. 33.

AASLD/IDSA Guidance

The AASLD/IDSA Guidance is an evolving, extensive, detailed, and complex publication that is periodically updated, most recently on May 24, 2018. Wilson Aff. at ¶ 14 and Ex. B, p. 4. Although the AASLD/IDSA Guidance advances aspirational and laudable public health statements, it does not create a standard of care for treatment of HCV. Wilson Aff. at ¶¶ 15-16. In fact, the website where the AASLD/IDSA Guidance is published contains a Medical Information Disclaimer providing that “[n]othing contained at HCVguidelines.org is intended to constitute a specific medical diagnosis, treatment, or recommendation. The information should not be considered complete, nor should it be relied on to suggest a course of treatment for a particular individual.” Wilson Aff. at ¶ 16 and Ex. B-1, p.1.

According to the AASLD/IDSA Guidance, accurately assessing fibrosis is “vital because the degree of hepatic fibrosis is one of the most robust prognostic factors used to predict HCV

¹ Dr. Wilson's affidavit is attached to Defendant's contemporaneously filed response to Plaintiffs' motion for a preliminary injunction.

disease progression and clinical outcomes.” Wilson Aff. at ¶ 13 and Ex. B, p. 32. As an informational and observational resource, the AASLD/IDSA Guidance notes treatment options based on HCV genotype, subtype, previous treatment history, degree of liver fibrosis, and other clinical issues. Wilson Aff. at ¶ 15. Those treatment options include lengthy and detailed information regarding the various possible DAA treatment regimens. Wilson Aff. at ¶ 21 and Ex. B, pp. 58-145.

Under the AASLD/IDSA Guidance, DAA regimen choice should consider patient specific data, including drug interactions and careful pretreatment assessment for comorbidities that may influence treatment response. Wilson Aff. ¶ 32 and Ex. B, pp. 58, 92. Consequently, according to the AASLD/IDSA Guidance, the administration of DAAs varies significantly according to indications, contraindications, dosing and duration, and drug interactions, and rarely involve the simple daily administration of a single pill, to a single patient, at the same time. Wilson Aff. at Ex. B, pp. 59-144. Importantly, the AASLD/IDSA Guidance explicitly recognizes the appropriateness of prioritization, noting that “in certain settings there remain factors that impact access to medications and the ability to deliver them to patients. In these settings, practitioners may still need to decide which patients should be treated first.” Wilson Aff. at ¶ 27 and Ex. B, p. 25.

HCV Treatment in State Correctional Settings and the Department’s Policy

The correctional environment generates several inherent challenges to treating HCV-infected inmates. The AASLD/IDSA Guidance notes that lack of expertise in HCV treatment is a common clinician-related barrier to treatment, and that lack of trained staff is one of the primary reasons that few inmates in correctional systems receive DAA treatment. Wilson Aff. at ¶ 25 and Ex. B, pp. 22, 210. The AASLD/IDSA Guidance also recognizes that costs may be a barrier to

providing DAA treatment, both in and outside of correctional settings. Wilson Aff. at ¶ 25 and Ex. B, pp. 22, 214.

Only 16% of prison facilities nationwide test all inmates for HCV upon entry. Similarly, only seventeen (17) states reported offering routine opt-out HCV testing in prison facilities, while only four states report adherence to the Clinical Guidelines of the Federal Bureau of Prisons (“the Federal Guidelines”). Wilson Aff. at ¶ 33 and Ex. B, pp. 210-11.

The Department’s HCV treatment policy prioritizes DAA treatment based on a patient’s individualized medical needs and history. Wilson Aff. at ¶ 34. The policy also provides for all patients (absent contraindications) with a fibrosis score of F2 or higher to be referred to a specialty Hepatology clinic for evaluation and, if warranted, administration of DAAs.

LAW AND ARGUMENT

A. Plaintiffs Cannot Establish That The Proposed Class Meets The Rule 23 Class Certification Standards

“The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.” *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (quotations omitted). A class action “may only be certified if the trial court is satisfied, after a *rigorous analysis*, that the prerequisites of Rule 23(a) have been satisfied.” *General Tel. Co. of the Southwest v. Falcon*, 457 U.S. 147, 161 (1982) (emphasis added). “Rule 23 is not a pleading standard. *Dukes*, 564 U.S. at 350. A party seeking class certification must *affirmatively demonstrate* his compliance with the Rule.” *Id.* at 350 (emphasis added).

Class certification first requires that the named plaintiff demonstrate that: 1) they are members of the proposed class, *see Fed. R. Civ. P. 23(a)* (“One or more members of a class may sue ... as representative parties on behalf of all members ...”), and that 2) the members of the proposed class are “readily identifiable” or “ascertainab[le].” *EQT Prod. Co. v. Adair*, 764 F.3d

347, 358 (4th Cir. 2014) (quotations omitted). The named plaintiffs must then establish that the four requirements of Rule 23(a) have been met. *Comcast Corp. v. Behrend*, ___ U.S. ___, ___, 133 S. Ct. 1426, 1432 (2013). Rule 23(a) requires the following:

- (1) the class is so numerous that joinder of all members is impracticable; (“numerosity”)
- (2) there are questions of law or fact common to the class; (“commonality”)
- (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; (“typicality”) and
- (4) the representative parties will fairly and adequately protect the interests of the class. (“adequacy”).

After satisfying the prerequisites established in Rule 23(a), the named plaintiffs must establish that the action falls within one of the three categories established in Rule 23(b). Plaintiffs seek class certification under Rule 23(b)(2), which requires that:

the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

Fed. R. Civ. P. 23(b)(2).

Here, three issues preclude class certification. First, Plaintiffs cannot establish that the class, as proposed, is ascertainable. Second, Plaintiffs cannot establish that their claims are typical of the class because the Department’s HCV treatment policies are applied based on individual assessments. Finally, Plaintiffs cannot establish that a Rule 23(b)(2) class is appropriate because the Department has not has acted or refused to act on grounds that apply generally to the class, and consequently, declaratory relief to the class as a whole is not appropriate.

1. The Class Is Not Ascertainable

“A class cannot be certified unless a court can readily identify the class members in reference to objective criteria.” *EQT*, 764 F.3d at 358. This requires that it be “administratively feasible for the court to determine whether a particular individual is a member [of the class].” 7A

Charles Alan Wright et al., Federal Practice & Procedure § 1760 (3d ed. 2005) (cited in *EQT*, 764 F.3d at 358). The importance of ascertainability is apparent given the requirement for a class action judgment to “include and describe those whom the court finds to be class members.” Fed. R. Civ. P. 23(c)(3)(A). While “[P]laintiffs need not be able to identify every class member at the time of certification,” the proposed class definition must be such that the class will be identifiable at the time of judgment. Fed. R. Civ. P. 23(c)(3)(A).

Here, the proposed class raises serious ascertainability issues. First, the class is defined to include both current and future prisoners in the Department’s custody without any time limit. However, the “current” population of prisoners in the Department’s custody changes every day as new inmates are incarcerated and others are released. And, no one can know the identities of all future prisoners. Accordingly, Plaintiff’s proposed class is incapable of definition, depriving this Court of the ability to ascertain the members of the class at the time of judgment.

Second, the proposed class requires knowing which prisoners have hepatitis C now and which will have it in the future. Plaintiffs acknowledge that this will require testing of all prisoners in the Department’s custody to determine the population of those inmates suffering from hepatitis C. D.E. 4 at 10. Plaintiffs assume that testing will occur because they have requested universal testing as relief in their motion for a preliminary injunction. *Id.* In Plaintiffs’ scenario, their ability to ascertain the class presumes their own success. However, the class must be ascertainable to the Court whichever party prevails, as this Court must ultimately enter a judgment identifying the members of the class. Fed. R. Civ. P. 23(c)(3)(A).

Plaintiffs also contend that “Defendants have the ability to readily identify all proposed class members.” D.E. 4 at 10. Plaintiffs cite no evidence in support of this contention, and also cite no authority for the proposition that Defendants must expend their own resources to ascertain

the members of a proposed class. In fact, the Supreme Court of the United States has imposed the duty on the party seeking class certification to “*affirmatively demonstrate* his compliance with the Rule.” *Dukes*, 564 U.S. at 350 (emphasis added). Because Plaintiffs cannot meet their own burden to ascertain the members of the class and the proposed class they do suggest is incapable of definition now or in the future, there is no way the Court could issue a future judgment and identify the class members. For this reason alone, the Court should deny class certification.

2. The Named Plaintiffs’ Claims Are Not Typical Of the Class Claims

To satisfy the typicality requirement, the claims of the named plaintiffs must be typical of the claims of the class. Fed. R. Civ. P. 23(a)(3). “This requirement is satisfied when the claims asserted by the named plaintiffs arise out of the same course of conduct and are based on the same legal theories as the claims of the unnamed class members.” *Hutson v. CAH Acquisition Co. 10 LLC*, No. 1:15CV742, 2016 WL 4289473, at *4 (M.D.N.C., Aug. 15, 2016) (internal quotations omitted). Here, Plaintiffs cannot establish that the Department’s decision not to provide certain HCV treatments—namely, DAAs—to the class members is based on the same course of conduct.

As provided in the Affidavit of Dr. Wilson, the Department’s decision to provide DAAs to inmates is based on an individual risk assessment that takes into account an inmate’s medical history (e.g., HIV and HBV infection status) and potential contraindications such as drug and alcohol use, pregnancy, mental health, and refusal to accept treatment. Wilson Aff. at ¶ 34 and Ex. D. For example, the Department may decide not to administer DAAs to an inmate who has a Stage 3 fibrosis score but also a drug or alcohol problem. See Wilson Aff. at Ex. D, p. 5 (listing contraindications). Alternatively, the Department might administer DAAs to an inmate who has a Stage 2 fibrosis score and an HIV infection. See *id.* Ex. B, p. 7. As there is no specific set of criteria governing—or precluding—particularized treatment to HCV-positive inmates, Plaintiffs

cannot demonstrate that the Department has acted with deliberate indifference to the class as a whole based solely on the Department's treatment decisions for the named Plaintiffs.

3. Certification Under Rule 23(B)(2) Is Not Appropriate Because The Department Has Not Acted Or Refused To Act Towards The Class In A General Manner

Plaintiffs also fail to meet their burden under Rule 23(b)(2), which requires that “the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.” Fed. R. Civ. P. 23(b)(2). “The key to the (b)(2) class is the indivisible nature of the injunctive or declaratory remedy warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.” *Dukes*, 564 U.S. at 360 (citation and quotation marks omitted).

Plaintiffs argue that the Department's HCV treatment policy violates the Eighth Amendment because it is deliberately indifferent to the class member's serious medical needs and they seek a declaratory judgment saying so. D.E. 1 at 22. The policy, however, is not a one-size fits all approach. As discussed in Section A.2, above, the policy calls for an individualized assessment of each inmate's medical needs. Therefore, in deciding whether the requested declaratory relief is warranted, this Court cannot consider the policy in general, but must look at the Department's assessments and treatment decisions for each class member. Plaintiffs' proposed class cannot properly be certified as a Rule 23(b)(2) class because the Court may find that the decision not to treat an HCV-positive inmate is lawful based on the individual's unique medical history. *See Dukes*, 564 U.S. at 360.

B. The Named Plaintiffs Lack Standing To Challenge The Department's HCV Screening Policies And Therefore Cannot Represent The Class On These Claims

Article III of the Constitution limits federal courts to adjudicating actual cases and

controversies, which requires, *inter alia*, that a plaintiff have standing to pursue each of their claims. *Doe v. Obama*, 631 F.3d 157, 160 (4th Cir. 2011). To satisfy that constitutional requirement, a plaintiff must allege that he:

(1) suffered an injury-in-fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.

Spokeo, Inc. v. Robins, ___ U.S. ___, ___, 136 S. Ct. 1540, 1547, (2016). These standing requirements apply equally to class actions.

In a class action, standing is evaluated “based on the allegations of personal injury made by the named plaintiffs.” *Hutton v. Nat’l Bd. of Examiners in Optometry, Inc.*, 892 F.3d 613, 620 (4th Cir. 2018). “The Supreme Court has made clear that named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.” *Doe*, 631 F.3d at 160 (internal quotation omitted) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n. 20 (1976)). While courts have allowed named plaintiffs to represent class members whose injuries sweep beyond their own, they have done so only when the named plaintiffs have first established that they, too, have been injured in some way by the conduct being challenged. See *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 591 (8th Cir. 2009) (citing *Sprint Communs. Co. v. APCC Servs., Inc.*, 554 U.S. 269, 275 (2008)).

Here, the Plaintiffs allege that the Department has “failed to implement medically adequate HCV screening practices” because it has “not implemented universal screening” but instead applies a risk-based screening approach. D.E. 1 at 2–3. Plaintiffs seek universal HCV screening as relief. D.E. 1 at 22; D.E. 26 at 1. However, because each of the named Plaintiffs has already been diagnosed with HCV and no longer requires screening, they lack standing to pursue a revised

screening policy on behalf of the putative class.

Named Plaintiff Robert Parham was diagnosed with hepatitis C prior to his incarceration with the Department. D.E. 3-2 at ¶ 1–2. In 2017, named Plaintiff Lloyd Buffkin “was diagnosed with hepatitis C while in [the Department’s] prison. D.E. 3-1 at ¶ 2. In 2015, named Plaintiff Kim Caldwell “was diagnosed with hepatitis C while in [the Department’s] prison.” D.E. 3-3 at ¶ 2. Plaintiff Caldwell was diagnosed within at most six months of entering the Department’s custody in July 2015. *Id.* at ¶ 1. Plaintiffs’ own allegations make clear that two of them were diagnosed with HCV *specifically as a result of* the Department’s existing screening process, and the other—Caldwell—was diagnosed within six months of incarceration. Accordingly, none of the named Plaintiffs were harmed by the Department’s HCV screening policy.

Unable to allege the existence of any injuries they personally suffered as a result of the Department’s screening policy, the named Plaintiffs contend that other inmates might be undiagnosed with HCV and require screening. D.E. 1 at 3. This is not sufficient to establish standing of the named Plaintiffs for any HCV screening claims. Moreover, Plaintiffs also lack standing because the relief requested—universal opt-out HCV screening—will provide them no relief or, frankly, even affect them. *See Spokeo*, 136 S. Ct. at 1547 (listing redressability as third element of standing); *Braden*, 588 F.3d at 591 (“That is, the question whether he has a cognizable injury sufficient to confer standing is closely bound up with the question of whether and how the law will grant him relief.”).

Because the named Plaintiffs do not have standing to bring claims challenging the Department’s HCV screening policy, they cannot demonstrate standing for purposes of the class. *See Hutton*, 892 F.3d at 620. For this reason, the Court should deny Plaintiffs’ motion to certify the class to the extent that the class claims include challenges to the Department’s HCV screening

policy.

CONCLUSION

To grant class certification, the party seeking certification carries the burden of satisfying Rule 23. Plaintiffs have not done so here. Plaintiffs have failed to carry their burden of proving both the ascertainability of the proposed class and the typicality of their claims as compared to the other class members. Plaintiffs have also failed to prove under Rule 23(b)(2) that the Defendants “ha[ve] acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.” Fed. R. Civ. P. 23(b)(2). Plaintiffs also lack standing to bring claims on behalf of the class related to the Department’s HCV screening policy. For these reasons, the Court should deny Plaintiffs’ motion for class certification.

This the 5th day of October 2018.

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CERTIFICATE OF WORD COUNT

Pursuant to Local Rule 7.3(d)(1), I certify that the body of this memorandum, including headings and footnotes but excluding the caption, signature lines, certificates and any cover pages or indices, does not exceed 6,250 words.

/s/ Orlando L. Rodriguez
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Assistant Attorney General

CERTIFICATE OF SERVICE

I hereby certify that on this day I electronically filed the foregoing **RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO CERTIFY CLASS** with the Clerk of the Court using the CM/ECF system, which will send notification to the following counsel of record:

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This the 5th day of October, 2018.

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